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PATENT

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I hereby certify that this correspondence is being transmitted by facsimile to Commissioner for Patents, Alexandria, VA, 22313-1450, Technology Center 1600, ATTN: Examiner Hamud at 703 872 9306 on

  
Jane A. Walker

June 24, 2004  
Date

Serial No: 09/971,902  
Conf. No.: 4028  
Filed: October 5, 2001  
Applicants: Oeltgen et al.  
Title: **METHOD FOR TREATING CYTOKINE  
MEDIATED HEPATIC INJURY**  
Art Unit: 1647  
Examiner: Hamud  
Attorney Docket: ZYM-09US

Cincinnati, Ohio 45202

June 24, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

DECLARATION OF PETER R. OELTGEN  
PURSUANT TO 37 C.F.R. §1.132

Sir:

I, PETER R. OELTGEN, declare as follows:

1. I am a named inventor in the above-identified patent application.

2. I hold a Ph.D. in biochemistry from Loyola University. I have over 30 years of experience in the field of metabolic inhibitors, which is the subject of the application.

3. I respectfully disagree with the Examiner's position that the claimed method is not described and enabled.

4. However, and only because the Examiner has requested evidence of use of the claimed peptide, I provide the requested data. The attachment, entitled "Deltorphan-D 24 Hour Survival Study", demonstrates use and efficacy of the claimed compound.

5. Specifically, control mice receiving saline alone (Group I), or saline and the claimed peptide (Group II), had normal ALT levels, indicating normal hepatic function. All mice induced for hepatic injury by administering endotoxin and galactosamine, and not treated with the claimed peptide (Group III), had increased ALT levels, ranging from 2500 to 3500 IU/L, and died (100% mortality).

6. In contrast, mice induced for hepatic injury by administering the identical concentrations of endotoxin and galactosamine, and receiving the claimed peptide (Group IV), had only 33.33% mortality, and decreased ALT levels of 640, 837, 956, and 1028 IU/L.

7. I respectfully assert that the claims are fully described and enabled, but now provide the additional information requested by the Examiner for the sole reason of advancing prosecution of this application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the subject application or any patent issued thereon.

6-24-04  
Date

  
Peter R. Ostgen, Ph.D.

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